



PC25051A
Information Disclosure Statement For Appln. No. 10/765,227

Certificate of Mailing (37 C.F.R. §1.8):

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s/ Rachel Potash
Rachel Potash

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:
ATSUO KUKI, et al.

Serial No.: 10/765,227

Confirmation No.: Not yet assigned

Filed: January 26, 2004

For: HIV INTEGRASE INHIBITORS,
PHARMACEUTICAL COMPOSITIONS, AND
METHODS FOR THEIR USE

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Honorable Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(b) or 1.97(c)

37 CFR § 1.97(b)

- ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

37 CFR § 1.97(c)

- ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); after three months of the date of entry of the national stage as set forth in § 1.491 in an international application; after the mailing of a first Office Action on the merits; or after the mailing of a first Office Action after the filing of a request for continued examination under § 1.114, but before the mailing date of (1) a Final Action under § 1.113; (2) a Notice of Allowance under § 1.311; or (3) an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the fee as set forth in § 1.17(p) to Deposit Account Number 500329.

- ☒ Applicant requests that the Examiner consider the following copending applications:

Application Serial No.	Filing Date
10/699,068	October 30, 2003

- ☒ Copies of these copending applications are enclosed.
- ☒ Applicant hereby requests consideration of the Information Disclosure Statement, USPTO form 1449, submitted herewith. Copies of the cited references, except as noted below, are enclosed.
- ☐ This application is a continuation, divisional or continuation-in-part of Serial No. [REDACTED]. Copies of the cited references, if not enclosed, are available in the file of the parent application or parents thereof.
- ☒ This application was filed after June 30, 2003, or entered U.S. national stage under 35 U.S.C. § 371, after June 30, 2003. Copies of U.S. Patents and U.S. Patent Application Publications are not enclosed. (1276 OG 55).
- ☐ Applicant hereby requests consideration of the enclosed International Search Report, which was received in a related international patent application.

Enclosed are a total of 52 references. Two references are in the German language. One contains an English abstract on its face; for the other, a CAS abstract is enclosed. Four references are in the Japanese language, for which Derwent abstracts are enclosed.

The Commissioner is hereby authorized to charge any fee deficiency, including any fee required under 37 C.F.R. § 1.17(p), or credit any overpayment, to Deposit Account Number 500329. A duplicate copy of this form is enclosed.

Respectfully submitted,

Date: May 4, 2004

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Substitute for form 1449/PTO

Complete if Known

Application Number	10/765,227
Filing Date	January 26, 2004
First Named Inventor	Atsuo Kuki
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	PC25051A

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)
U.S. PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. ¹	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ²			
	AA	10/699,068	Filed on 10-30-2003	Agouron Pharmaceuticals, Inc.	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	AB	WO 02/070491 (English abstract enclosed)	09-12-2002	Shionogi & Co., Ltd.		
	AC	JP 2003119137 (English abstract enclosed)	04-23-2003	Japan Tobacco, Inc.		
	AD	WO 03/035076	05-01-2003	Instituto Di Richerche Di Biologa Molecolare P. Angeletti Spa		
	AE	WO 03/047564 (English abstract enclosed)	06-12-2003	Shionogi & Co., Ltd.		
	AF	WO 03/049690	06-19-2003	Bristol-Myers Squibb Company		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	AG	JP 2003171381 (counterpart is WO 2003035650 for which English abstract is enclosed)	06-20-2003	Takeda Chemical Industries, Ltd.		
	AH	WO 03/062204	07-31-2003	Merck & Co., Inc.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AI	ABDEL-MAGID, et al., "Reductive Amination of Aldehydes And Ketones With Sodium Triacetoxyborohydride. Studies On Direct And Indirect Reductive Amination Procedures," <i>Journal of Organic Chemistry</i> , 1996, 3849-3862, Vol. 61.	
	AJ	BAGSHAW, K. et. al., "Antibody-Directed Enzyme Prodrug Therapy: A Review," <i>Drug Development Research</i> , 1995, 220-230, Vol. 34.	
	AK	BARBIER, C., et al., "Preparation of Lavendamycin Analogues," <i>Heterocycles</i> , 2000, 37-48, Vol. 53, No. 1.	
	AL	BERTOLINI, G. et. al., "A New Rational Hypothesis for the Pharmacophore of the Active Metabolite of Lefluonamide, a Potent Immunosuppressive Drug," <i>J. Med. Chem.</i> , 1997, 2011-2016, Vol. 40.	
	AM	BIERE, H., et al., "Eine Neue und Besonders Einfache Synthese Von Zentralaktiven β -Carbolin-Derivaten," <i>Liebigs Ann. Chem.</i> , 1986, 1749-1764 (see English abstract).	
	AN	BODOR, N., "Novel Approaches to the Design of Safer Drugs: Soft Drugs and Site-Specific Chemical Delivery Systems," <i>Advances in Drug Research</i> , 1984, 255-331, Vol. 13.	
	AO	BUNDGAARD, et al., <i>Design of Prodrugs</i> , 1985, Elsevier Press.	
	AP	BUNDGAARD, H. "Design and Application of Prodrugs", <i>Drug Design Application and Development</i> , 1991.	
	AQ	BUTLER, S.L., et al., "A Quantitative Assay for HIV DNA Integration <i>In Vivo</i> ," <i>Nature Medicine</i> , May 2001, 631-634, Vol. 7, No. 5.	
	AR	CAMPBELL, K.N., et al., "The Preparation of Unsymmetrical Secondary Aliphatic Amines," <i>J. Am. Chem. Soc.</i> , 1944, 82-84, Vol. 66.	

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AS	CHEN, B. et al., "Distinct Modes Of Human Immunodeficiency Virus Type 1 Proviral Latency Revealed By Superinfection Of Nonproductively Infected Cell Lines With Recombinant Luciferase-Encoding Viruses," <i>Journal of Virology</i> , 1994, 654-660, Vol. 68, No. 2.
AT	DEAR, G.J. et. al., "Mass Directed Peak Selection, an Efficient Method of Drug Metabolite Identification Using Directly Coupled Liquid Chromatography-Mass Spectrometry-Nuclear Magnetic Resonance Spectroscopy," <i>Journal of Chromatography B</i> , 2000, 281-293, Vol. 748.
AU	DEBYSER, Z., et al., "Assays for the Evaluation of HIV-1 Integrase Inhibitors," <i>Methods in Molecular Biology</i> 160, 139-155. SCHEIN, C.H., Humana Press Inc., Totawa, NJ 2001.
AV	DEKHANE, M., et al., "A New Efficient Synthesis of Ethyl β -Carboline-3-Carboxylate (β -CCE) and Methyl 4-Methyl- β -Carboline-3-Carboxylate (4-Methyl- β -CCM) Starting From Indole-2 Carbolxaldehyde," <i>Tetrahedron</i> , 1994, 6299-6306, Vol. 50, No. 21.
AW	DOYLE, et al., "Nuclear Analogs of β -lactam Antibiotics. I. Synthesis of O-2-isoccephams," <i>Can. J. Chem.</i> , 1977, 468-483, Vol. 55.
AX	EBERLE, M., "Contribution To The Chemistry Of Indole. About The 5-(1-Indolyl)-2-Pentanone System," <i>Journal of Organic Chemistry</i> , 1976, 633-636, Vol. 41, No. 4.
AY	ELIEL, E.L., et al., <i>Stereochemistry of Organic Compounds</i> , Wiley, New York, 1994.
AZ	EROFEEV, Y.V., et al., "Introduction of 3-Indolymethyl Residues in Nitroacetic Acid Esters," <i>Khim. Get. Soed.</i> , 1978, 780.
BA	GOLDGUR, Y., et al., "Structure Of The HIV-1 Integrase Catalytic Domain Complexed With An Inhibitor: A Platform For Antiviral Drug Design," <i>PNAS</i> , November 9, 1999, 13040-13043, Vol. 96, No. 23.
BB	GROBLER, J. et al., "Diketo Acid Inhibitor Mechanism And HIV-1 Integrase: Implications For Metal Binding In The Active Site Of Phosphotransferase Enzymes," <i>PNAS</i> , May 14, 2002, 6661-6666, Vol. 99, No. 10.
BC	HANSEN, M.S., et al., "Integration Complexes Derived From HIV Vectors For Rapid Assays In Vitro," <i>Nature Biotechnology</i> , June 1999, 578-582, Vol. 17, No. 6.
BD	HAUSER, C.R., et al., <i>Org. Synth. Coll.</i> , Vol. 2., 1943, 67, John Wiley, New York.
BE	HAZUDA, D. et al., "Discovery And Analysis Of Inhibitors Of The Human Immunodeficiency Integrase," <i>Drug Design And Discovery</i> , 1997, 17-24, Vol. 15.

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BF	JENKINS, T.M., et al., "A Soluble Active Mutant of HIV-1 Integrase," <i>Journal of Biological Chemistry</i> , 1996, 7712-7718, Vol. 271, No. 13.
BG	KANTLEHNER, W., et al., "Umsetzungen von <i>tert</i> -Butoxy-N,N,N',N'-tetramethylmethandiamin mit Nh- und CH-aciden Verbindungen," <i>Liebigs Ann. Chem.</i> , 1980, 344 (see English abstract).
BH	LEWIN, S.R., et al., "Use of Real-Time PCR and Molecular Beacons to Detect Virus Replication in Human Immunodeficiency Virus Type 1-Infected Individuals on Prolonged Effective Antiretroviral Therapy," <i>Journal of Virology</i> , July 1999, 6099-6103, Vol. 73, No. 7.
BI	LYTTLE, D.A., et al., "The Chemistry of Nitroacetic Acid and Its Esters. I. The Alkylation of Alkyl Nitroacetates with Gramine," <i>J. Am. Chem. Soc.</i> , 1947, 2118-2119, Vol. 69.
BJ	MARCH, JERRY, <i>Advanced Organic Chemistry</i> , 5 th Edition, 508-511, John Wiley & Sons, 2001.
BK	NEEF, G., et al., "Synthesis of 4-Substituted β -Carbolines," <i>Heterocycles</i> , 1983, 1295-1313, Vol. 20, No. 7.
BL	PAIS, G., et al., "Structure Activity of 3-Aryl-1,3-diketo-Containing Compounds as HIV-1 Integrase Inhibitors," <i>Journal of Medicinal Chemistry</i> , 2002, pp. 3184-3194, Vol. 45.
BM	PROX, et. al., "Rapid Structure Elucidation of Drug Metabolites by Use of Stable Isotopes," <i>Xenobiotica</i> , 1973, 103-112, Vol. 3 No. 2.
BN	SANDRIN, J., et al., "Pictet-Spengler Condensations in Refluxing Benzene," <i>Heterocycles</i> , 1976, 1101-1104, Vol. 4, No. 6.
BO	SAYASITH, K., et al., "Targeting HIV-1 Integrase," <i>Expert Opin. Ther. Targets</i> , 2001, 443-464, Vol. 5, No. 4.
BP	SETTIMJ, et al., " β -Carbolines as Agonistic or Antagonistic Benzodiazepine Receptor Ligands. 1. Synthesis of some 5-, 6- and 7-Amino Derivatives of 3-Methoxycarbonyl- β -carboline (β -CCM) and of 3-Ethoxycarbonyl- β -Carboline (β -CCE)," <i>J. Heterocycl. Chem.</i> , 1988, 1391-1397, Vol. 25.
BQ	SHAN, D. et al., "Prodrug Strategies Based On Intramolecular Cyclization Reactions," <i>J. Pharm. Sci.</i> , 1997, 765-767, Vol. 86, No. 7.
BR	SNYDER, H.R., et al., "The Synthesis of the 2-Amino-3-(3-indolyl)-butyric Acids (β -Methyltryptophans)," <i>J. Am. Chem. Soc.</i> , 1957, 2217-2221, Vol. 79.
BS	SPRAUL, et al., "Liquid Chromatography Coupled with High-Field Proton NMR for Profiling Human Urine for Endogenous Compounds and Drug Metabolites," <i>J. Pharmaceutical & Biomedical Analysis</i> , 1992, 601-605, Vol. 10, No. 8.

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	BT	STILL, W., et al., "Rapid Chromatographic Technique For Preparative Separations With Moderate Resolution," <i>Journal of Organic Chemistry</i> , 1978, 2923-2925, Vol. 43, No. 14.	
	BU	SUNDBERG, et al., "Syntheses With N-Protected 2-Lithioindoles," <i>Journal of Organic Chemistry</i> , 1973, 3324-3330, Vol. 38, No. 19.	
	BV	TERWILLIGER, E.F., et al., "Construction and Use of a Replication-Competent Human Immunodeficiency Virus (HIV-1) That Expresses the Chloramphenicol acetyltransferase Enzyme," <i>Proc. Natl. Acad. Sci., USA</i> , May 1989, 3857-3861, Vol. 86.	
	BW	WAI, J. et al., "4-Aryl-2,4-Dioxobutanoic Acid Inhibitors Of HIV-1 Integrase And Viral Replication In Cells," <i>Journal of Medicinal Chemistry</i> , December 28, 2000, 4923-4926, Vol. 43, No. 26.	
	BX	WEISLOW, O.S., et al., "New Soluble-Formazan Assay for HIV-1 Cytopathic Effects: Application to High-Flux Screening of Synthetic and Natural Products for AIDS-Antiviral Activity," <i>J. Natl. Cancer Inst.</i> , April 19, 1989, 577-586, Vol. 81, No. 8.	
	BY	YOUNG, S.D., et al., "Inhibition of HIV-1 Integrase by Small Molecules: The Potential for a New Class of AIDS Chemotherapeutics," <i>Curr. Opin. Drug Disc. & Devel.</i> , 2001, 402-410, Vol. 4, No. 4.	
	BZ	YOUNG, S., et al., "L-870, 810: A Potent Antiviral HIV Integrase Inhibitor with Potential Clinical Utility," Poster presented at International AIDS Conference, Barcelona, (July 7-12, 2002).	

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